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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,443

12/20/2006

Hitoshi Kotani

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EXAMINER

CHEN, STACY BROWN

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,443	<b>Applicant(s)</b> KOTANI ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 69-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 69-91 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The preliminary amendment filed September 26, 2006 is acknowledged and entered.  
Claims 69-91 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The inventions listed as Groups I-XXXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The asserted special technical feature that links the inventions is a viral envelope that enhances an immune response in an animal. The prior art discloses a method of gene transfer that uses a virus envelope from Sendai virus (hemagglutinating virus of Japan) as a vector for transferring genes (see EP 1170363 A1, abstract). Therefore, because the asserted special technical feature is anticipated by the prior art the claims lack unity of invention.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 69 and 70 link(s) inventions I-VIII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 69 and 70. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable**

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**linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- I. Claims 71 and 72, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of a **hemagglutinating virus of Japan**.
- II. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of a **retrovirus**.
- III. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of an **adenovirus**.
- IV. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of an **adeno-associated virus**.
- V. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of a **herpes virus**.

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VI. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of a **vaccinia virus**.

VII. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of a **pox virus**.

VIII. Claim 71, drawn to a method for enhancing an immune response comprising administering an effective amount of an envelope of an **influenza virus**.

Claims 73 and 79-83 link(s) inventions IX-XVII. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 73 and 79-83. In addition to the election of one of Groups IX-XVII, Applicant is also required to elect one of a hemagglutinating virus of Japan, a retrovirus, an adenovirus, an adeno-associated virus, a herpes virus, a vaccinia virus, a pox virus and an influenza virus. Election of a single virus is not a species election.

IX. Claims 74-88, drawn to a pharmaceutical composition comprising **bleomycins** encapsulated in a viral envelope vector having an adjuvanticity.

X. Claims 74 and 77, drawn to a pharmaceutical composition comprising **anthraquinone series carcinostatics** encapsulated in a viral envelope vector having an adjuvanticity.

XI. Claims 74 and 77, drawn to a pharmaceutical composition comprising **mitomycins** encapsulated in a viral envelope vector having an adjuvanticity.

XII. Claims 74 and 77, drawn to a pharmaceutical composition comprising **actinomycins** encapsulated in a viral envelope vector having an adjuvanticity.

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XIII. Claims 74 and 77, drawn to a pharmaceutical composition comprising

**camptothecins** encapsulated in a viral envelope vector having an adjuvanticity.

XIV. Claims 74 and 77, drawn to a pharmaceutical composition comprising **cisplatin**s

encapsulated in a viral envelope vector having an adjuvanticity.

XV. Claims 74 and 77, drawn to a pharmaceutical composition comprising

**streptozotocin** encapsulated in a viral envelope vector having an adjuvanticity.

XVI. Claims 74 and 77, drawn to a pharmaceutical composition comprising **5-FU**

encapsulated in a viral envelope vector having an adjuvanticity.

XVII. Claims 74 and 77, drawn to a pharmaceutical composition comprising

**pirarubicin** encapsulated in a viral envelope vector having an adjuvanticity.

Claims 84, 85, 87 and 88 link(s) inventions XVIII-XXVI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 84, 85, 87 and 88.

XVIII. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a

hemagglutinating virus of Japan and **adriamycin**.

XIX. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a

hemagglutinating virus of Japan and **daunomycin**.

XX. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a

hemagglutinating virus of Japan and **aclarubicin**.

XXI. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a

hemagglutinating virus of Japan and **amrubicin**.

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XXII. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a hemagglutinating virus of Japan and **idarubicin**.

XXIII. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a hemagglutinating virus of Japan and **epirubicin**.

XXIV. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a hemagglutinating virus of Japan and **pirarubicin**.

XXV. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a hemagglutinating virus of Japan and **dacarbazine**.

XXVI. Claim 86, drawn to a pharmaceutical composition comprising an envelope of a hemagglutinating virus of Japan and **mitoxantrone**.

Claims 89 and 90 link(s) inventions XXVII-XXXV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 89 and 90.

XXVII. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of hemagglutinating virus of Japan and **adriamycin**.

XXVIII. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of a hemagglutinating virus of Japan and **daunomycin**.

XXIX. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of a hemagglutinating virus of Japan and **aclarubicin**.

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XXX. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of a hemagglutinating virus of Japan and **amrubicin**.

XXXI. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of a hemagglutinating virus of Japan and **idarubicin**.

XXXII. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering an envelope of a hemagglutinating virus of Japan and **epirubicin**.

XXXIII. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering comprising an envelope of a hemagglutinating virus of Japan and **pirarubicin**.

XXXIV. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering comprising an envelope of a hemagglutinating virus of Japan and **dacarbazine**.

XXXV. Claim 91, drawn to a method for the treatment of urological cancer in an animal, comprising administering comprising an envelope of a hemagglutinating virus of Japan and **mitoxantrone**.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the



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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

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the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/

Primary Examiner, Art Unit 1648